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Charles J. Davidson

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CROMPTON, SEAGER & TUFTE, LLC
1221 NICOLLET AVENUE
SUITE 800
MINNEAPOLIS, MN 55403-2420

EXAMINER

MATTHEWS, WILLIAM H

ART UNIT

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3774

MAIL DATE

DELIVERY MODE

02/03/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Response to Arguments

Applicant's arguments filed 8-7-07 have been considered but are not persuasive.

Regarding the rejections under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, Applicant provides support for having the transducer positioned to transmit signals through the stent's side opening but the specification fails to support the limitation "in axial and radial alignment with the side opening". In particular, "radial alignment" also encompasses a transducer positioned at the same radial distance as the side opening which was not disclosed in the specification as filed nor in the provisional application.

With regard to the rejection under 35 U.S.C. 103(a), Applicant contends each of the cited references fails to disclose a transducer in axial and radial alignment with a stent opening, nor motivation to provide such an arrangement. Examiner disagrees because the references teach the use of transducers to aid in visualization and locating for vascular procedures and having transducers placed on a vascular catheter. The additional step of aligning the opening and transducer would have been readily apparent to one of ordinary skill in the art because the purpose of the procedure is to align the opening of the stent with a branch vessel.

Priority

The claims receive priority benefit of parent application 09/669,060 filed September 22, 2000. The claims do not receive priority benefit of provisional application 60/155,611 filed September 23, 1999 because they are not fully supported

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by the provisional application. The effective filing date of the claims is September 22, 2000.

Applicant failed to adequately provide specifics regarding the application being identical or the subject matter being fully supported by the earlier filed applications, specifically, the provisional application (60/155,611). The limitation regarding axial and radial alignment is not supported.

Claim Objections

Claim 25 objected to because of the following informalities: "an" should be amended to ---a---. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 23,25,26,28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The amendment to the claims to include the limitation of "stent in axial and radial alignment with the side opening" is not clearly supported in the original specification. In particular, "radial alignment" encompasses a

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transducer positioned at the same radial distance as the side opening which was not disclosed in the specification as filed nor in the provisional application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 23,25,26,28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Von Oepen (6048361) in view of O'Connor (6398792 as cited in applicant's IDS), Solomon (5846204) and Jang et al (USPN 5,749,848 as cited in applicant's IDS).

Von Oepen discloses a stent delivery system for use in a body lumen with all the elements of the claim, but is silent to an ultrasound transducer being disposed near the catheter body distal end. See Figure 3 for catheter (30) comprising a catheter body having a distal end, proximal end, a longitudinal axis and a lumen, an expansion device (balloon) disposed near the catheter body distal end, and a stent (20) disposed over the expansion device. See Figure 2 and column 2, lines 66-67 for the stent (20) having a wall comprising struts and connectors forming multiple passageways (21) and further comprising a side hole (22) that is adapted to provide access to a side branch.

O'Connor teaches an ultrasonic catheter system, which includes an ultrasound transducer. While the transducer is used for treatment of the vascular system, it is known in the art to use the transducer for location application as taught by Jang et al.

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Furthermore, O'Connor teaches use of the transducer for visualization before and after an operation (column 4, lines 1-4). It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to modify the stent delivery system of Von Oepen to include an ultrasound imaging transducer disposed inside the expansion device in order to determine exactly where the diseased segment of the blood vessel begins and ends and to correctly position the stent such that the side hole is positioned at the ostium of a branch vessel. This would replace the completely separate x-ray contrast means and x-ray screen for visual monitoring used by Von Oepen for positioning the side hole, thus simplifying the procedure. The examiner contends that use of this ultrasound transducer instead of x-ray will provide the surgeon with more accurate, informative and controllable images of the diseased vessels for side hole positioning.

With regard to the housing of claims 25 and 28, Solomon teaches in Figure 1, a rotatable ultrasound catheter (100) with a transducer housing for imaging. A guidewire is accepted through the passage (114) in order to prevent unintended deflection of the transducer as it is rotated around the guidewire for three-dimensional imaging. See column 5, lines 1-14. Because the guidewire sleeve portion (108) is *integral with* the housing portion (104), the transducer housing is rightfully interpreted as including both portions (104 and 108) (column 5, lines 19-22). It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of O'Connor and/or Solomon to modify the stent delivery system of Von to include a transducer housing with a passage coupled to the transducer and a guidewire disposed

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in the passage. This ensures that the ultrasound transducer travels in a predetermined path around the guidewire maintained in the passage, which is configured to maintain the planar surface of the transducer substantially parallel with a portion of the guidewire that is located within the passage. The imaging device with transducer can be positioned directly over the guidewire through the passage and advantageously reduce operating time.

Allowable Subject Matter

Claim 12 is allowed.

Conclusion

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Matthews (Howie) whose telephone number is 571-272-4753. The examiner can normally be reached on Monday-Friday 10-6:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David J. Isabella can be reached on 571-272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/William H. Matthews/
Primary Examiner
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